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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REGULATORY AUTHORITY

OCT 31 20

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Alan Curtis
Aragon Surgical, Inc.
1810 Embarcadero Road, Suite B
Palo Alto, CA 94303

NAME OF DEVICE

Trade Name:	Aragon Surgical RF System
Common Name:	Electrosurgical System
Device Product Code:	GEI
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

PREDICATE DEVICES

- LiagSure ™ Vessel Sealing System (K981916)
- LigaSure™ Open Dissector Divider (K041587)

DEVICE DESCRIPTION

The Aragon Surgical RF System consists of the Aragon Surgical Radiofrequency Energy (RF) Generator and a handheld Instrument, foot pedal, and power cord. The Aragon Surgical Instrument connects to the RF Generator. The Aragon Surgical Instrument is supplied sterile and is intended for single use. The Instrument uses a bipolar design, which means that a return pad is not required for operation.

Software is utilized in the operation of the Aragon Surgical RF Generator.

K081312

INDICATION FOR USE STATEMENT

The Aragon Surgical System is indicated for tissue sealing and division during the performance of abdominal hysterectomy. The instrument can seal vessels up to 7mm.

This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

SUBSTANTIAL EQUIVALENCE COMPARISON

Comparison to Predicate Devices

The technological characteristics and indications for use of the Aragon Surgical System are similar to those of the cited predicate electrosurgical devices, as well as the similar RF Systems distributed by other manufacturers. These devices are equivalent in terms of design, materials, principal of operation, and product specifications. Any differences between the Aragon Surgical System and the predicate devices do not raise new issues regarding safety or effectiveness.

PERFORMANCE DATA

Results of bench and pre-clinical evaluations were used to demonstrate that the Aragon Surgical System is substantially equivalent to the predicate devices and meets design, safety, and effectiveness criteria.

CONCLUSION

Based on the design, materials, function, intended use, and pre-clinical evaluation, the Aragon Surgical System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Sufficient data were obtained to demonstrate that the device is substantially equivalent to the predicate devices and raises no new safety or effectiveness issues. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance for commercial sale.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Aragon Surgical
% Mr. Alan Curtis, RAC
VP, Regulatory/Clinical & Quality
Affairs
1810 Embarcadero Road, Suite B
Palo Alto, California 94303

Re: K081312
Trade/Device Name: Aragon Surgical Radiofrequency (RF) System and accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 10, 2008
Received: October 14, 2008

Dear Mr. Curtis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number: K081312

Device Name: Aragon Surgical Radiofrequency (RF) System

Indications for Use:

The Aragon Surgical RF System is indicated for tissue sealing and division during the performance of abdominal hysterectomy. The instrument can seal vessels up to 7mm.

This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use_____X_____ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081312